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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/162,101	09/28/98	KISSEL T	514429-3665

HM12/1223

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EXAMINER	
NGUYEN,D	
ART UNIT	**PAPER NUMBER**
1633	8

DATE MAILED: 12/23/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/162,101	Kissel et al.
Examiner	**Group Art Unit**
Dave Nguyen	1633

☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *1* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-19, 21, 23-25, and 30-43* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims *1-19, 21, 23-25, and 30-43* are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group I. Claims 1-14, 21, 35, 23, 30, drawn to a vector comprising a LMW PEI and a DNA, and methods of making the vector, classified in Class 435, and subclass 320.1.

Group II. Claims 30, 38 and 39, drawn to pharmaceutical compositions comprising a LMW PEI and a DNA, and an *in vivo* gene therapy method comprising the step of administering to any subject a vector comprising a LMW PEI and a DNA, classified in class 514, subclass 44.

Group III. Claims 24, 25, 33, 36, and 40-43, drawn to transfected cell comprising the vector, and *in vitro* methods for making the transfected cells, and *ex vivo* gene therapy method comprising the step of administering to any subject genetically modified cells expressing a DNA which is transfected by a vector comprising a LMW PEI and the DNA, classified in Class 435, subclass 325, and Class 424, subclass 93.21.

Group IV. Claims 15-19, 32, 34, 37, drawn to a process for preparing a LMW PEI, pharmaceutical compositions comprising the LMW PEI, classified in class 424, 486.

The inventions are distinct, each from the other because of the following reasons:

Group II and Group III employ distinct inventions for the reasons set forth below:

The *ex vivo* Gene therapy claimed in Groups III employs materially distinct step, *e.g.,* administration of genetically modified cells expressing a therapeutic protein and/or DNA, and the *in vivo* gene therapy cited in Group II comprises materially distinct steps, *e.g., in vivo* administration of DNA sequences encoding a therapeutic protein and/or DNA to a subject or target cells from the subject. Thus, the materially distinct steps generate different modes of operation, and different effects.

Invention I and Invention II, and III are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the vectors of Invention I are not limited in the processes cited in inventions II to III and can be used for

production of protein molecules and/or antibodies *in vitro* or expansion of genetically modified cells *in vitro.* Each is dinstinct in the art and is independently searched for prior art which would anticipate or render obvious each composition under 35 USC 102 or 103. In addition, considerations regarding 35 U.S.C. 112 are independent and distinct in its operation, function, and effect. Thus, it would be a serious burden for the examiner to search all claims of Inventions I, II, and III.

Groups I, II, III, and Group IV are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination of Group I which are also encompassed by the claimed processes of Groups III and IV does not require the particulars of the subcombination as claimed in Group IV, *e.g.,* addition of boron trifluoride rather than addition of acid catalysts. The specific subcombination as recited in the claimed invention of Group IV has separate utility such as the use of the LMW PEI prepared by the process of claim 19 in the delivery of drugs and proteins.

Should Group I be elected, this application also contains claims directed to the following patentably distinct species of the claimed invention:

1/ The vector of claim 1 which is a viral nucleic construct; and

2/ The vector of claim 1 which is a non viral construct.

Applicant is further required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 1 is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed

generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Should Group I be elected, this application also contains claims directed to the following patentably distinct species of the claimed invention:

The effector gene of claim 7, 8, and 9, in which the effector gene is selected from the group consisting of the coding sequence of a pharmacological active compound or its prodrug form, the coding sequence of an enzyme; the coding sequence of a fusion protein comprising an enzyme fused to a cell-specific ligand.

Applicant is further required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1 and 6 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant

should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Should Group I be elected, this application also contains claims directed to the following patentably distinct species of the claimed invention:

- The vector of claim 1 wherein the ratio by weight of LMW PEI to nucleic acid is 3:1 or more.
- The vector of claim 1 wherein the ratio by weight of LMW PEI to nucleic acid is 8:1 or more.

Applicant is further required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1 and 6 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their divergent subject matter, fall into different statutory classes of invention, and are separately classified and searched, restriction for examination purposes as indicated is proper.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to *Dave Nguyen* whose telephone number is **(703) 305-2024**.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, *John Leguyder*, may be reached at **(703) 305-7028.**

Any inquiry of a general nature or relating to the status of this application should be directed to the *Group receptionist* whose telephone number is **(703) 304-0196**.

Dave Nguyen

Patent Examiner

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